November 7, 2023

Zhejiang Soudon Medical Technology Co.,Ltd
% Nick Wang
RA Specialist
Shanghai Vanhe Consulting Co., Ltd
Shanghai, 201703
CHINA

Re: K232476
Trade/Device Name: Disposable Sphincterotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS
Dated: July 18, 2023
Received: August 16, 2023

Dear Nick Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal,Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232476

Device Name
Disposable Sphincterotome

Indications for Use *(Describe)*
The Disposable Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device is supplied sterile and intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Submitter

Submitted by:	Zhejiang Soudon Medical Technology Co.,Ltd Address:Room 302-1,Floor 3, Building 4, No.1 Nangonghe Road, Donghu Street, Linping District, Hangzhou 311100 Zhejiang, China
Contact Person:	Nick Wang RA Specialist Shanghai Vanhe Consulting Co., Ltd Address: 2F, Building No.1, 3938 Huqingping Road, Qingpu District, Shanghai, China. Phone: 0086-13585860297 Email: vanheconsulting@126.com
Date Prepared:	July 24, 2023

Device

Device Name:	Disposable Sphincterotome
Classification Name:	unit, electrosurgical, endoscopic (with or without accessories)
Regulatory Class:	II
Regulation Number:	21 CFR 876.4300
Regulation Name：	Endoscopic electrosurgical unit and accessories
Product Code:	KNS

Predicate Device

Device Name:	Sphincterotome, K201121
Manufacturer:	Hangzhou AGS MedTech Co., Ltd.
Classification Name:	unit, electrosurgical, endoscopic (with or without accessories)
Regulatory Class:	II
Regulation Number:	21 CFR 876.4300
Regulation Name：	Endoscopic electrosurgical unit and accessories
Product Code:	KNS

2. Device Description

The Disposable Sphincterotome described in this submission are a sterile, single use

devices compatible with the working channel of endoscope. The device consists of a long plastic tube with a wire running the length of its interior. A small portion of that wire is exposed at its distal end. The roof of the papilla is opened by passing high-frequency current through the wire, exposing the biliary or pancreatic orifices for selective cannulation.
The models with injection can inject contrast medium into the biliary ducts. The main materials of the proposed device include PTFE, ABS, SUS304. Type A, Type B and Type C are included in this submission.
The proposed devices are EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 3 years.

3. Indication for Use:
The Disposable Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device is supplied sterile and intended for single use only.

4. Comparison of Technological Characteristics
The Disposable Sphincterotome has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Hangzhou AGS MedTech Co., Ltd.'s Sphincterotome, K201121. The differences between the proposed device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Disposable Sphincterotome(**Proposed Device**)	Sphincterotome, K201121	Discussion
Indication for Use	The Disposable Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device is supplied sterile and intended for single use only.	The Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device is supplied sterile and intended for single use only.	Same
Product Code	KNS	KNS	
Regulation Number	878.4300	878.4300	Same
Class	2	2	Same
Supplied in	Yes	Yes	Same

Item	Disposable Sphincterotome(**Proposed Device**)	Sphincterotome, K201121	Discussion
Sterile			
Principles of Operation	The product reaches the duodenal papilla through the working channel of the duodenoscope, and the cutting wire of the product uses the thermal effect produced by high-frequency current to dehydrate and proteinize the tissue at the duodenal papilla to achieve the purpose of incision of the tissue.	Sphincterotome manufactured is an applied part of electrosurgical generator, using monopolar high frequency current delivered by the electrosurgical generator for sphincterotomy with the electrode. The high frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	Same
Injection	Contrast Medium	Contrast Medium	Same
Wire Guide Diameter	0.89mm	0.63mm, 0.89mm	Similar
Minimum Accessory Channel	2.4mm	2.8mm	Similar
Working Length	2000mm	1800mm	Similar
Energy Used/Delivered	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
SAL	10^{-6}	10^{-6}	Same
Sterilization Method	EO Sterilization	EO Sterilization	Same
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Same

5. Non-clinical Performance Data

The proposed device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135-1 “Sterilization of Health Care products Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals” .

The following bench tests were performed on Disposable Sphincterotome: Appearance, Physical properties. The results of all testing were passing.

6. Clinical Test Data

No Clinical Study is included in this submission.

7. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Zhejiang Soudon Medical Technology Co.,Ltd has demonstrated that proposed device Disposable Sphincterotome is substantially equivalent to Hangzhou AGS MedTech Co., Ltd.’s currently marketed Sphincterotome, K201121.